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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,716	11/30/2000	David F. O'Brien	15907-0022	4843

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/728,716

Applicant(s)
O'Brien

Examiner
Gollamudi S. Kishore, Ph.D

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 0
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what 'freeze thawing-extrusion' in claim 30 indicates. Is it freeze thawing followed by extrusion?

The comma after consisting of in claim 33 should be deleted.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-4, 9-11, 16-17, 19, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamparski (Biochemistry, vol. 31., 1992) of record.

Lamparski discloses liposomes containing a phospholipid and a polymerizable colipid (note the abstract, Materials and Methods and Discussion). The polymerizable lipid upon polymerization with ultra-violet radiation polymerizes and destabilizes the liposomes thereby leaking the contents.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 9-11, and 16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamparski cited above.

The teachings of Lamparski have been discussed above. In essence, Lamparski teaches instant liposomes and the destabilizing effect of ultra-violet on the liposomal membrane. Although Lamparski does not teach a method of administration of a therapeutic agent of a diagnostic agent, based on the studies Lamparski suggests the applicability of the ionizing radiation induced destabilizing of the liposome and the regulation of the release of the biological agents (note page 693). It would have been

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therefore, obvious to one of ordinary skill in the art to use the liposomes of Lamparski for the delivery of the diagnostic or therapeutic agents with a reasonable expectation of success since Lamparski provides guidance as to how to prepare the liposomes and suggests their use. Lamparski teaches only the of the application of ultraviolet radiation as the source as the ionizing radiation. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to use any form of ionization as long as they polymerize the lipid.

7. Claims 5-8 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamparski cited above in view of Woodle (BB, 1992) of record.

Lamparski does not teach the inclusion of PEG in the liposomal composition.

Woodle discloses that the inclusion of hydrophilic polymers such as PEG in liposomes stabilizes the liposomes and also improves the circulation time of these sterically stabilized liposomes when administered (pages 180-185 and 194-195).

The inclusion of PEG in liposomes of Lamparski would have been obvious to one of ordinary skill in the art since such an inclusion stabilizes the liposomes and also improves their circulation time when administered.

8. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamparski cited above by itself or in combination with Woodle also cited above, further in view of Hallahan (6,159,443) or vice versa.

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The teachings of Lamparski have been discussed above. In essence, Lamparski teaches instant liposomes and the destabilizing effect of ultra-violet on the liposomal membrane. Although Lamparski does not teach a method of administration of a therapeutic agent or a diagnostic agent, based on the studies Lamparski suggests the applicability of the ionizing radiation induced destabilizing of the liposome and the regulation of the release of the biological agents (note page 693). It would have been therefore, obvious to one of ordinary skill in the art to use the liposomes of Lamparski for the delivery of the diagnostic or therapeutic agents with a reasonable expectation of success since Lamparski provides guidance as to how to prepare the liposomes and suggests their use. Lamparski teaches only the use of the application of ultraviolet radiation as the source as the ionizing radiation and not other forms such as X-rays.

Hallahan discloses X-ray guided drug delivery to treat various neoplasms. The method involves administering the therapeutic agent or diagnostic agent in a delivery vehicle (liposomes) and irradiating the tissue using X-rays. The liposomes also contain antibodies attached to them. According to Hallahan such a method improves the drug delivery to the desired tissues (note the abstract, col. 1, line 61 through col. 6, line 58, col. 7, line 65 through col. 9, line 18, col. 15, line 18 through col. 17, line 9, col. 20, lines 6-49, col. 23, lines 10-59, Examples and claims).

The use of X-rays as the ionizing radiation with the liposomes of Lamparski would have been obvious to one of ordinary skill in the art since X-rays are not only another form

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of ionizing radiation to destabilize the liposomes in delivering the contents, but also provide an improved method of delivery when combined with delivery vehicles such as liposomes.

Alternately, to use the liposomes of Lamparski as the liposomes in Hallahan since Lamparski's liposomes release the active agent at the desired site when the X-rays polymerize the polymerizable lipid, thus providing an added advantage.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 22, 2002